



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 19, 2020

Cristina Griffin
Agent for Disinfexol LLC
c/o Delta Analytical Corp.
12510 Prosperity Drive, Suite 160
Silver Spring, MD 20904

Subject: PRIA Label Amendment –Add Human Coronavirus and qualify for List N
Product Name: Disinfexol
EPA Registration Number: 95747-1
Application Date: May 11, 2020
Decision Number: 564497

Dear Ms. Griffin:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. The next label printing of this product must use this labeling unless subsequent changes have been approved. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website

Page 2 of 2
EPA Reg. No. 95747-1
Decision No. 564497

contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Assurance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Andrés Garzón by phone at (703) 347-8547, or via email at GarzonMoreno.Andres@epa.gov.

Sincerely,



Jacqueline Hardy
Product Manager 34
Regulatory Management Branch II
Antimicrobial Division(7510P)

Enclosure Stamped Label

DISINFEXOL

Hospital HOCl Cleaner and Disinfectant

- Kills bacteria *Pseudomonas aeruginosa* [ATCC 15442] and *Staphylococcus aureus* [ATCC 6358] on hard, non-porous surfaces in 5 minutes
- Kills Human Coronavirus [ATCC VR-740] on hard, non-porous surfaces in 5 minutes
- Ready-To-Use Product

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

ACTIVE INGREDIENTS:

Hypochlorous Acid0.065%

OTHER INGREDIENTS99.935%

TOTAL INGREDIENTS100.000%

See back [side] panel for precautionary statements [and first aid]

EPA Reg. No.: 95747-1

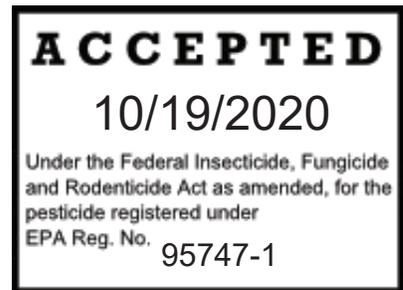
EPA Est. No.:

Manufactured by [or for]:

Disinfexol LLC

401 Professional Drive, Ste. 220

Gaithersburg, MD 20879



Expiration Date: _____

[Note to reviewer: Expiration date will be stamped with date of 4 months after production date, in accordance with shelf-life data]

Net Contents: _____

FIRST AID: Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center, doctor, or going for treatment. You may also contact the National Pesticide Information Center (NPIC) 1-800-858-7378 for emergency medical treatment information. **IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS AND DOMESTIC ANIMALS: Caution: Causes moderate eye irritation. Avoid contact with eyes. When handling this product, wear safety glasses or goggles. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

PHYSICAL OR CHEMICAL HAZARDS: Disinfexol is not compatible with other chemicals such as acids and hydrogen peroxide.

About: Disinfexol is a Hospital HOCl Cleaner and Disinfectant for hard, non-porous surfaces.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This product cleans and disinfects against the following organisms in 5 minutes of contact time: Pseudomonas aeruginosa, Staphylococcus aureus, and Human Coronavirus.

Where to use: Effective on hard, non-porous surfaces in Hospitals, Clinics, Healthcare Facilities, Schools, Government and Office Buildings. Avoid contact with painted and unfinished wood surfaces. Refill only with this product.

To [Clean and] Disinfect [and Deodorize] Hard, Non-Porous Surfaces: For visibly soiled areas, a preliminary cleaning is required to remove all visible soil. Apply Disinfexol [this product] to hard, non-porous surfaces until thoroughly wet with a cloth, wipe, mop, sprayer, or sponge. For spray application: Hold nozzle 6-8 inches from surface. Spray until thoroughly wet. Treated surfaces must remain visibly wet for 5 minutes. Allow surfaces to air dry. Do not use on utensils, glasses or dishes.

This product is not to be used as a terminal sterilant / high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical devices prior to sterilization or high-level disinfection.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Storage: Store in a closed dark [*or opaque*] plastic container in a cool, dry area away from heat and direct sunlight. Do not store near easily oxidizable materials, acids and reducers. In case of spill, isolate container (if possible) and flood area with water to dissolve all material before discarding container in trash.

Product Disposal: Product rinsates that cannot be used should be diluted with water before disposal in a sanitary sewer.

[Institutional uses, non-refillable container 5 gallons or less]

Container Handling: Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. To clean the container before final disposal, triple or pressure rinse. Follow Pesticide Disposal instructions for rinsate disposal. Offer for recycling if available or place in trash.

[For Institutional uses, refillable container]

Refillable container. Refill this container with bleach only. Do not re-use this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, triple or pressure rinse. Follow Pesticide Disposal instructions for rinsate disposal. Offer for recycling if available or puncture and dispose of in a sanitary landfill.

[Optional graphics to be used anywhere on the label:]

Made in USA

Recycle icon

[Barcode]

[Text in brackets/italics is optional or instructional]